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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,729	04/22/2002	Raphael Darteil	ST99021 US PCT	5011

22852 7590 08/26/2003

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[REDACTED] EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,729	DARTEIL ET AL.	
	Examiner Robert M Kelly	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 December 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding PPAR α .

Group II, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding PPAR γ .

Group III, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding modified PPAR α .

Group IV, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding modified PPAR γ .

Group V, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding PPAR α and a ligand for PPAR α .

Group VI, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding PPAR γ and a ligand for PPAR γ .

Group VII, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding modified PPAR α and a ligand for PPAR α .

Group VIII, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding modified PPAR γ and a ligand for PPAR γ .

Group IX, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding PPAR α and additionally encoding an RXR under the control of a transcriptional promoter.

Group X, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding PPAR γ and additionally encoding an RXR under the control of a transcriptional promoter.

Group XI, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding modified PPAR α and additionally encoding an RXR under the control of a transcriptional promoter.

Group XII, claim(s) 1-23, 25-27, 29 and 31, drawn to a nucleic acid encoding modified PPAR γ and additionally encoding an RXR under the control of a transcriptional promoter.

Group XIII, claim(s) 24, 28, and 29, drawn to in vivo use of PPAR α .

Group XIV, claim(s) 24, 28, and 29, drawn to in vivo use of PPAR γ .

Group XV, claim(s) 24, 28 and 29, drawn to in vivo use of modified PPAR α .

Group XVI, claim(s) 24, 28 and 29, drawn to in vivo use of modified PPAR γ .

Group XVII, claim(s) 32, 33, drawn to a method of identification of PPAR α ligands.

Group XVIII, claim(s) 32, 33, drawn to a method of identification of PPAR γ ligands.

Group XIX, claim(s) 32, 33, drawn to a method of identification of PPAR α ligands *in vivo*.

Group XX, claim(s) 32, 33, drawn to a method of identification of PPAR γ ligands *in vivo*.

The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature shared by groups I and II is a composition comprising a first nucleic acid of interest under control of an inducible promoter comprising a PPRE and a minimal transcriptional promoter; however, groups I and II lack a special technical feature because they are comprised of distinct, PPAR α or PPAR γ sequences, as recognized in the art (below). The special technical feature shared by groups I and II is described in WO 98/21349. WO 98/21349 describes a novel construct for the inducible expression of genes *in vivo*, *ex vivo*, and *in vitro* (ABSTRACT), which includes an inducible promoter comprising a PPRE and a minimal transcriptional promoter (e.g., Figure 3, phA-II (J3), J = PPRE, -210/+29 = transcriptional promoter, and CAT = nucleic acid of interest). Furthermore, PPAR α and PPAR γ are distinct

sequences because they (i) bind to different consensus DNA sequences (SPECIFICATION, p. 10), (ii) have different tissue distributions (Lee, et al. (2003) Endocrinology 144(6): 2201-07, 2201), (iii) have different biological activities (Id.), and bind different biological molecules (Id., Figure 1). Groups III and IV have as a special technical feature modified forms of PPAR α or PPAR γ with unexpected responses. Groups V-VIII have as a special technical feature the addition of ligands specific to each PPAR α or PPAR γ to induce PPAR-activated transcription. Groups IX-XII have as a special technical feature the addition of a gene encoding an RXR protein. Groups XIII-XVI has as a special technical feature the in vivo use of PPARs. Groups XVII-XX have as a special technical feature a method of identifying novel PPAR ligands.

Furthermore, the special technical feature shared by Groups I and III-XX is the same as that between groups I and II. As set forth above, each of the Groups has a “special technical feature” not required for the other groups.

Thus, Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1.

Groups I-XX represent separate and distinct products, which are not provided for by 37 C.F.R. §§ 1.475 (b) or (d). Hence, restriction is required.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (703) 305-4460. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

August 18, 2003


DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
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